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Pain Policy in the US: Are We Moving Forward?

**American Pain Society
Boston, 2005**

**David E. Joranson
Pain & Policy Studies Group
University of Wisconsin Medical School
World Health Organization Collaborating Center
www.medsch.wisc.edu/painpolicy**



Media coverage about pain

Chronic Pain Under Treated, Expert Says

Omaha World-Herald 08 Mar 1999

Cancer Pain Still Under Treated

British Medical Journal, Nov 25, 2000

Experts Say Cancer Pain Under Treated

The Associated Press, 7/18/2002

Pain is Under Treated in African Americans

AORN Journal, Oct, 2002

Chronic Pain Management is a Sorely Ignored Topic

Baltimore Sun 10 Nov 2003

Media coverage about war on painkillers

The War on Painkillers

New York Times 29 Jan 2002

Doctors: Patient Care Losing to War on Drugs

Decatur Daily 26 Oct 2003

Painkillers: The New Villain in the Drug War

Atlanta Journal Constitution 6 Jan 2004

Doctors Cautious with Pain Prescriptions

Roanoke Times 23 May 2004

A War on Drugs or a War on Healing?

Tallahassee Democrat 5 Jan 2004

Objectives

- **Progress**
 - Improving knowledge of state medical regulators
 - Model policy development
 - More “balanced” state laws, regulations and guidelines
- **Set-backs**
 - Perception that opioid prescriptions are responsible for increased opioid abuse
 - DEA interim policy statement
- **Recommendations**

Education and research with medical regulators

- ✓ **3 National surveys of medical board members
(1991, 1997, 2004)**
- ✓ **14 state and regional workshops
(1994-present)**

Prescribing an opioid analgesic for more than several months to treat a patient with:

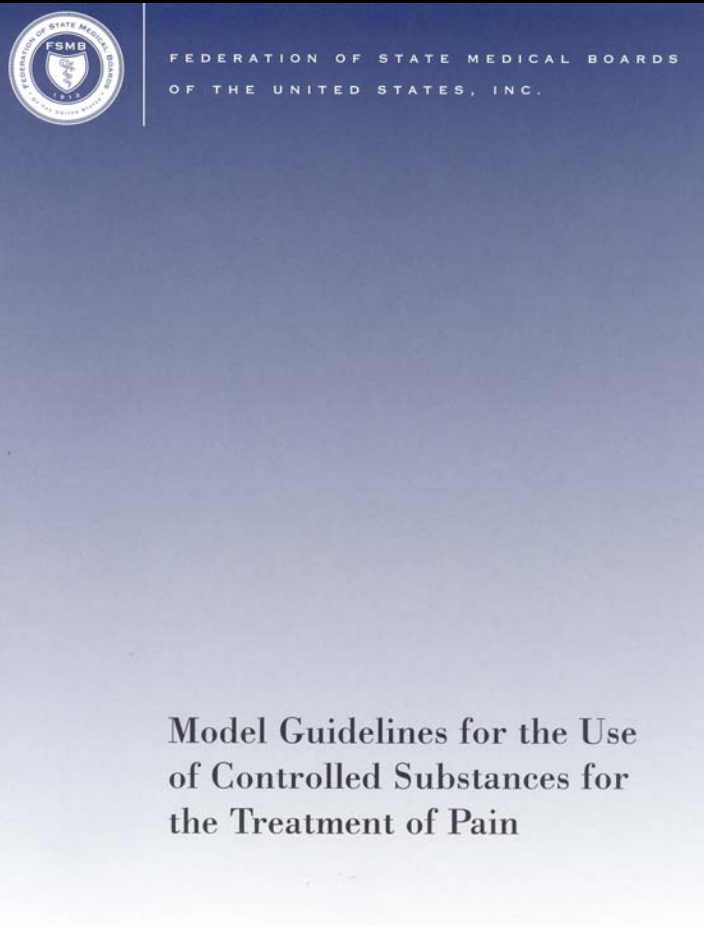
**Lawful/generally
acceptable medical practice?
(1991, 1997, 2004)**

Chronic cancer pain:	75%, 82%, 87%*
Chronic cancer pain/Hx abuse:	46%, 57%, 65%*
Chronic non-cancer pain:	12%, 33%, 67%*
Chronic non-cancer pain/Hx abuse:	1%, 6%, 21%*

* Significantly higher than on previous surveys

Model Policy Development

- ✓ **FSMB Model Guidelines (1998)**
- ✓ **FSMB Model Policy (2004)**

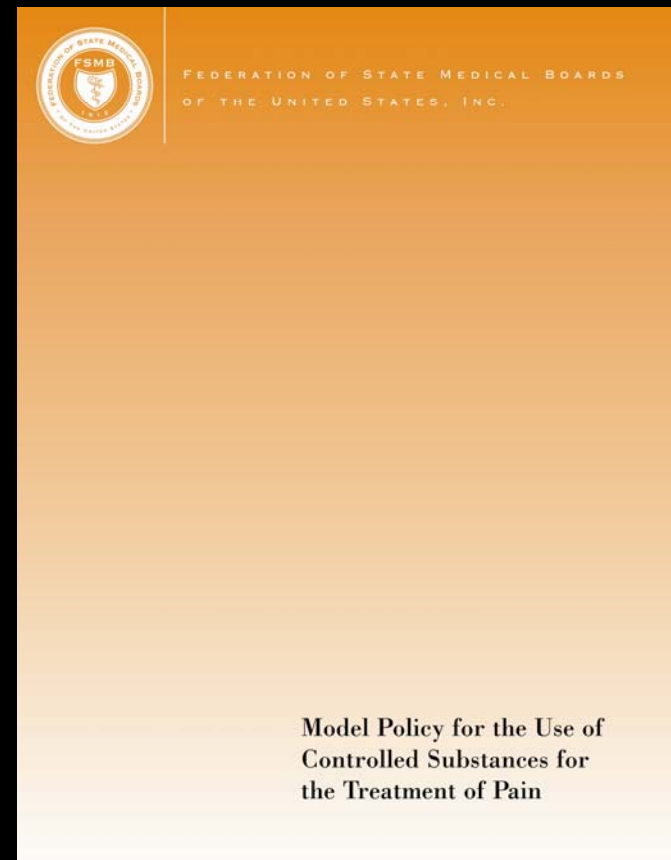


13 states

Adopted in full

12 states

Adopted in part



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FSMB Model Policy

- ✓ **Pain relief part of quality medical practice**
- ✓ **Recognizes need for opioids**
- ✓ **Recognizes potential for abuse**
- ✓ **Need for examination, diagnosis and monitoring**
- ✓ **Prescription quantity not an indicator**

FSMB Model Policy

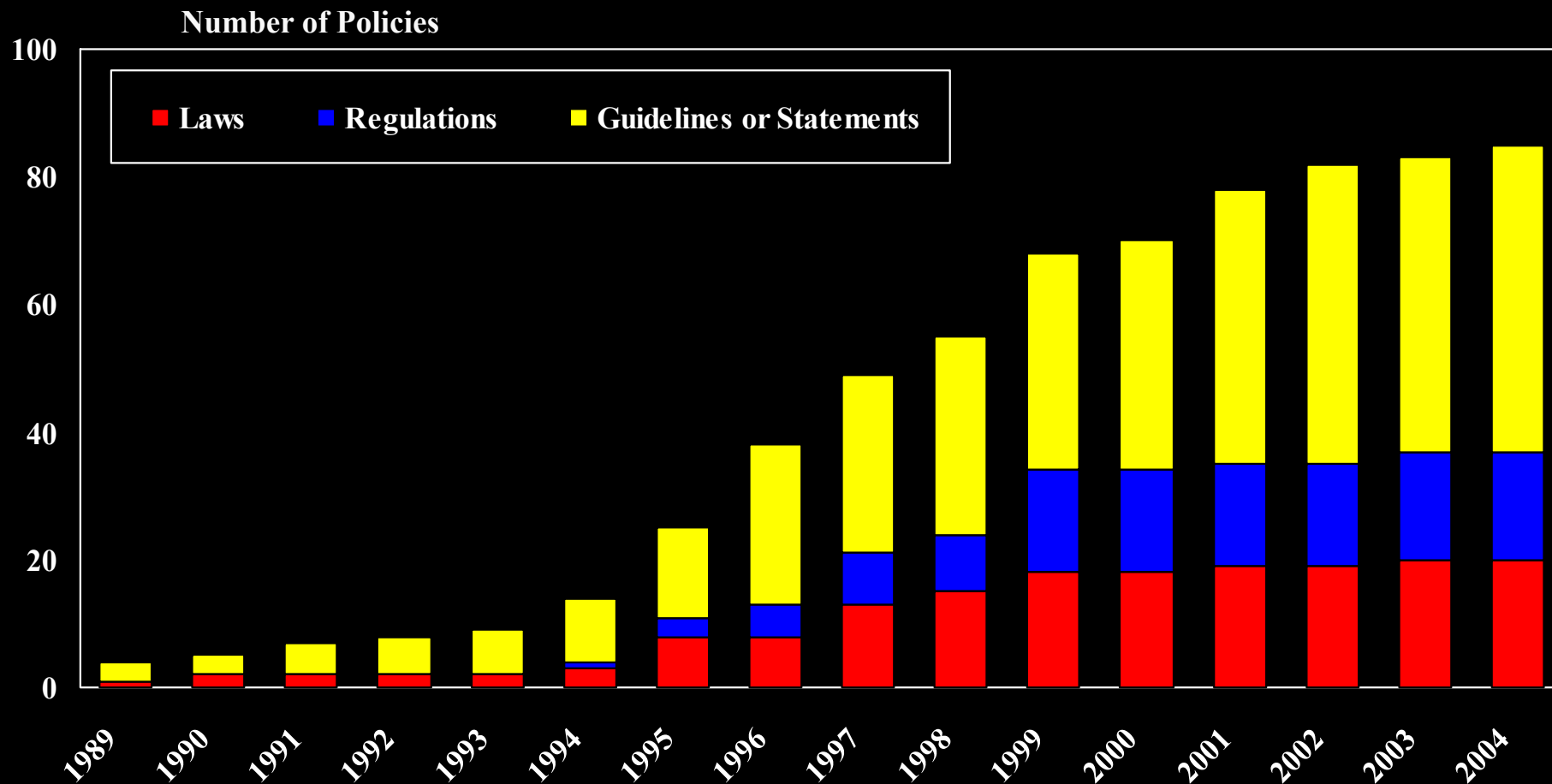
- ✓ **Current definitions**
- ✓ **Should not fear investigation**
- ✓ **Documentation**
- ✓ **Compliance with laws**
- ✓ **Inappropriate tx includes over, under, non-treatment, continued ineffective tx**

Evaluating and improving state pain policy

- ✓ **Tracking state policy trends**
 - Pain policies in nearly all states
- ✓ **2 evaluations of national policy**
(2000-2003)
- ✓ **Progress Report Card (2003)**

State Pain-Specific Policies

1989 - 2004



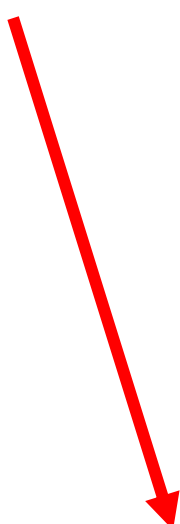
Welcome to the
Pain & Policy Studies Group
University of Wisconsin
Comprehensive Cancer Center



World Health Organization Collaborating Center
for Policy and Communications in Cancer Care

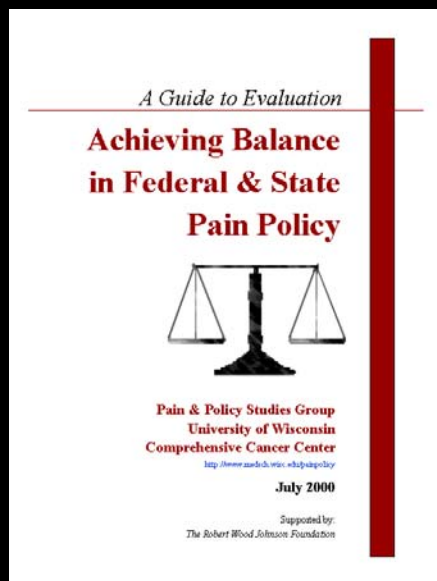
***"Promoting pain relief by improving
public policy and communications"***

If you are interested in being added to our email news distributist, please click [here](#)

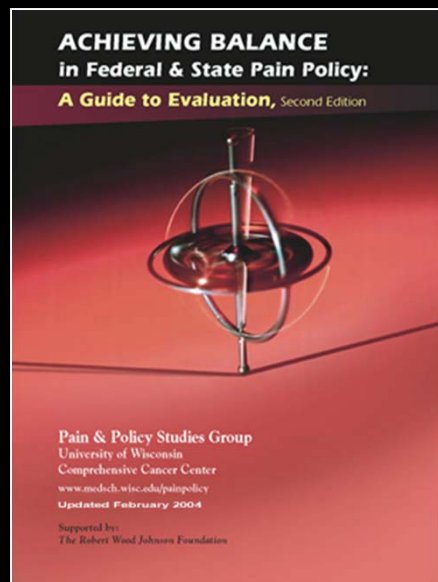


**Database of Statutes,
Regulations,
& Other policies**

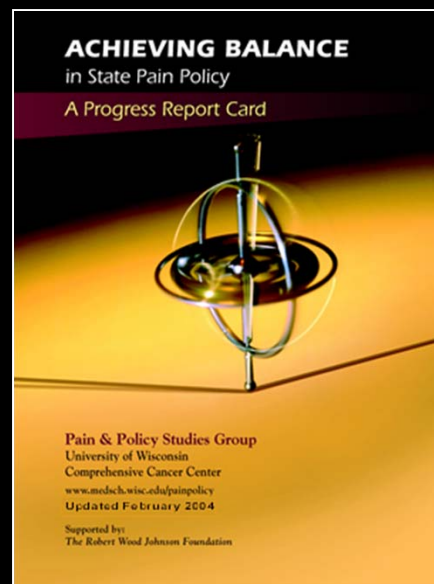
Sequence of PPSG Policy Evaluations



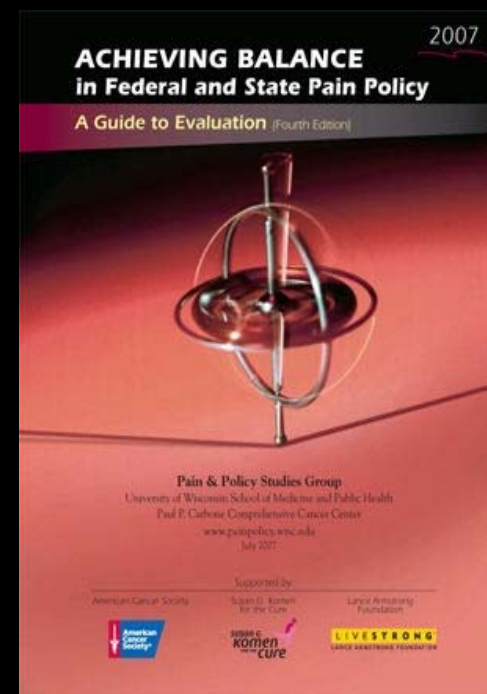
2000



2003



2006



2007

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Evaluation and Benchmarking State Pain Policies

- **Central principle (Balance)**
- **Derive evaluation criteria (17)**
- **Peer review of evaluation methodology**
- **Collect policies**
 - **Laws, regulations, guidelines (377 in 2003)**
 - **Pain, controlled substances, medical and pharmacy practice**
- **Evaluate policies (3 researchers)**
- **Analyze, report results (EG1, EG2, PRC)**

The Principle of “Balance”

Central to protecting public health and safety

- **Opioids are safe and effective, necessary**
- **Opioids have potential for abuse, pose risks**
- **“Controlled substance” status not intended to diminish medical usefulness of opioids**
- **Policy governing medicine and drugs should be consistent with medical and scientific knowledge**
- **Underlying medical/legal accountability not disturbed**
- **Efforts to address diversion must not interfere with medical practice and patient care**

Recognition of the Principle of “Balance”

- **Institute of Medicine**
- **National Cancer Institute**
- **Federation of State Medical Boards**
- **National Assn of Attorneys General**
- **American Medical Association**
- **American Pain Society**
- **State pain initiatives**
- **Drug Enforcement Administration (?)**

16 States Improved Pain Policies (2000-2003)

Florida

Hawaii

Idaho

Iowa

Kansas

Kentucky

Massachusetts

Michigan

Missouri

Nevada

New Mexico

Ohio

South Carolina

Tennessee

West Virginia

Wisconsin

Examples of Policy Changes

- **Addition of positive provisions**
 - ✓ Encourage pain management
 - ✓ Pain management part of quality professional practice
 - ✓ Address fear of regulatory scrutiny
 - ✓ Correctly define addiction
 - ✓ Rx quantity not indicator
 - ✓ Tx of addicts with pain
 - ✓ Encourages risk assessment
- **Repeal of negative provisions**
 - ✓ PMP with special government form
 - ✓ Short validity periods (2 weeks or less)
 - ✓ Mandated consultation

Pain policies have been adopted and revised by:

- **State legislatures**
- **State licensing boards**
 - **Medicine**
 - **Nursing**
 - **Pharmacy**

Catalysts for Change

- **Federation of State Medical Boards**
- **State Pain Initiatives**
- **Community-State Partnerships**
- **End-of-Life Care Coalitions**
- **ACS Divisions**
- **Leadership of key individuals**

Message 1

Government agencies in the states increasingly understand barriers to pain management and are acting to achieve clear and more balanced policies.

Use and abuse trends

2000 **1st Assessment of use and abuse
1990-1996 (JAMA)**

2004 **2nd Assessment of use and abuse
1997-2002 (JPSM)**

www.medsch.wisc.edu/painpolicy

‘Opioid abuse has increased, as have prescriptions’

- **Supported by data from several sources**
- **Are increased prescriptions for opioid analgesics, i.e., increased “availability,” the cause of increased abuse?**
- **What is the relationship between increasing prescriptions and abuse?**

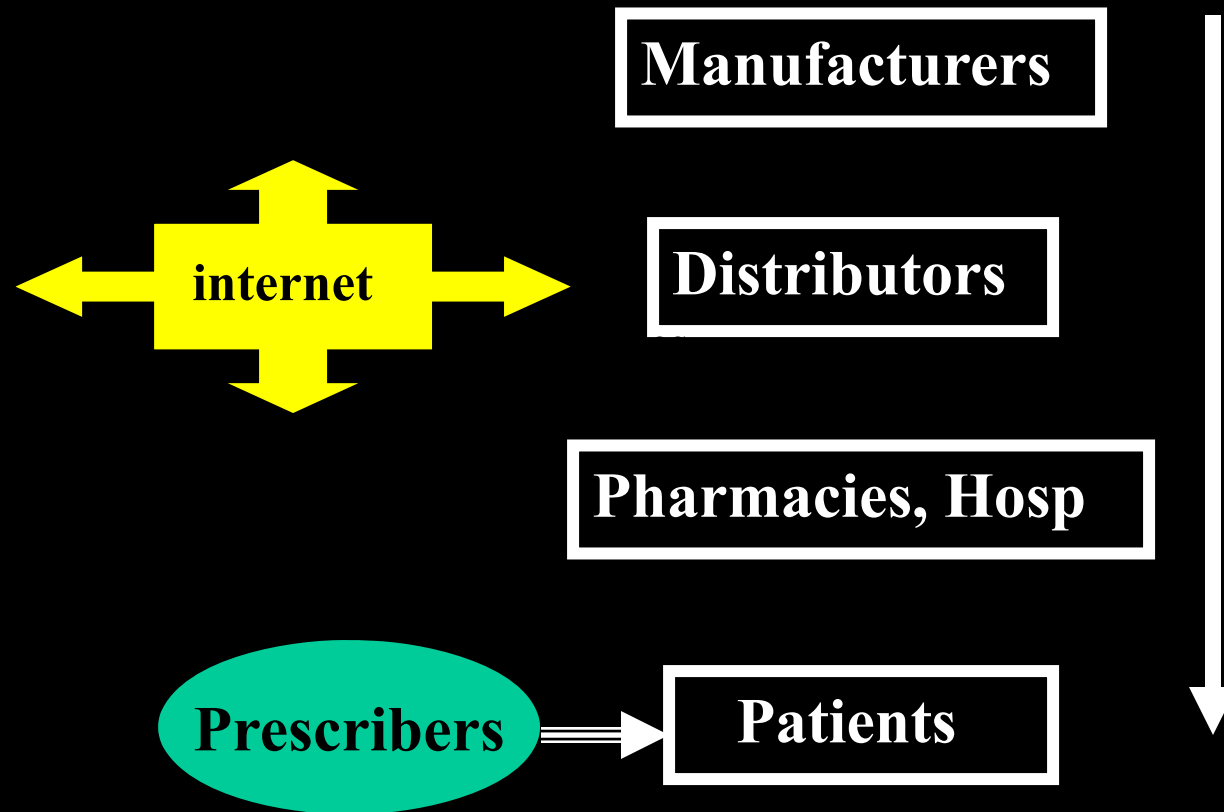
“If the abuse of opioid analgesics should increase, the sources of diversion should be addressed directly without interfering with medical availability of opioid analgesics, legitimate medical practice, or patient care.”

Joranson et al. Trends in medical use and abuse of opioid analgesics. *Journal of the American Medical Association*. (2000).

What is ‘diversion’

- **Illegal movement of prescription drugs such as opioids out of the licit system to illicit channels of distribution and use.**
- **Many possibilities for “leaks” in the drug distribution system:**
 - **Pill mills**
 - **Shoppers/Rx fraud**
 - **Prescribers**
 - **Patients**
 - **Theft**
 - **Internet**

Drug distribution system



Is there data on source and quantity of diversion from anywhere in the system?

2002: > 45 pharmacy robberies and thefts in Boston area (media reports)

2000-2003 2,494 thefts of Oxycontin
631 armed robberies
707 night break-ins
1,369,667 dosage units (DEA)

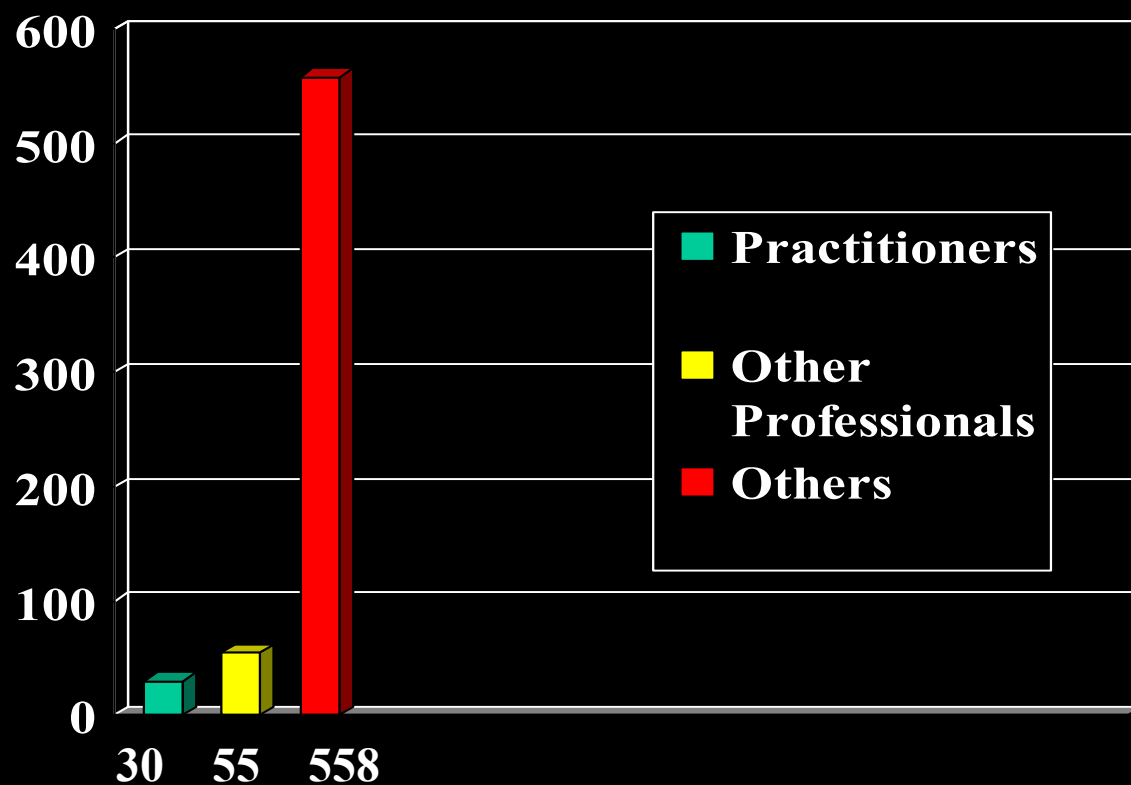
Theft data: opioid analgesics

(manufacturers, distributors, pharmacies)

- **Pharmacy theft a federal crime**
- **Reporting of significant losses required**
- **DEA 106 form**

- **New, raw data from 106 system (preliminary)**
- **2000-2003 (4y)**
- **Fentanyl, Hydrocodone, Hydromorphone, Meperidine, Methadone, Morphine, Oxycodone**
- **Pharmacy stocks rise in proportion to prescriptions**

DEA arrests for diversion of oxycodone and hydrocodone (FY 2004)



Message 2

- **The reasons for increased abuse should be studied, taking into consideration all the sources of abused opioids, including deliberate criminal activities to divert opioids from all levels of the distribution system. Source and amount matter.**
- **Meanwhile, we should ensure that efforts to address abuse and diversion do not interfere in pain management.**

Balancing roles of clinicians and law enf.

	CLINICIANS	LAW ENF./REG.
Primary	<ul style="list-style-type: none">• Evaluate patients' pain• Relieve pain	<ul style="list-style-type: none">• Evaluate sources of diversion• Stop diverters
Secondary	<ul style="list-style-type: none">• Know about diversion• Avoid contributing to diversion	<ul style="list-style-type: none">• Know about pain management• Avoid interfering in medicine and patient care



U.S. Department of Justice
Drug Enforcement Administration

In partnership with:
Last Acts Partnership
Pain & Policy Studies Group,
University of Wisconsin

Prescription Pain Medications



Last Acts Partnership

Advocating Quality
End-Of-Life Care

PAIN & POLICY STUDIES GROUP
University Of Wisconsin-Madison Medical School

Frequently Asked Questions
and Answers for Health Care
Professionals and Law
Enforcement Personnel

The “FAQ”

- **DEA initiated-to encourage more balance**
- **To educate clinicians, law enforcement**
- **30 Questions**
 - Terminology
 - Pain mgt/Rx quantity
 - Risk assessment
 - Pts with addiction
 - Regulatory requirements and issues
- **DEA, Last Acts, PPSG + experts**
- **~ 20 drafts**

The “FAQ”

- **Conceived: Nov 02**
- **Born: Aug 11 04 (~21 months)**
- **Terminated: Oct 4 04 (<2 months)**
- **DEA Interim Policy Statement Nov 16 04**
 - Reversed previous interpretations
- **DEA Request for comments Jan 18 05**
 - Comments were due Mar 21 05

www.medsch.wisc.edu/painpolicy/DEA/index.htm

PPSG Recommendations to DEA

- (1) Reinstate previous interpretation permitting ‘prescription series’ (“do not fill until...”)**
- (2) Use appropriate indicators of diversion**
- (3) Clarify unlawful conduct**
- (4) Stop sending messages of fear**
- (5) Communicate strong commitment to a balanced national policy and enforcement**
- (6) Endorse the FSMB Model Policy**
- (7) Appoint an Advisory Committee**

Message 3

Although states are making significant advances in pain policy, recent federal law enforcement policy has been a setback for pain management and must be corrected.

DEA's commitment to APS

“It is critical that we let the public know [that] law enforcement and the health community are working together. We are not at odds...We made a commitment at that press conference to achieving a balanced approach to the prescribing and regulating of opioids. My message to you tonight is that we stand by that commitment.”

Administrator Asa

Hutchinson

14 May 2019

Recommendations for APS

- **APS ask Analgesic Regulatory Affairs Cmte**
 - **To review DEA final policy statement and prepare analysis and recommendations for the Board of Directors;**
 - **To recommend to the Board ways the Association can support efforts to improve federal and state pain policies, their administration and enforcement**
- **APS members and chapters**
 - **Seek opportunities to communicate and build understanding with federal and state regulators and law enf.**